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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,292	07/03/2001	Michele Amouyal	1231-01	2241

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IP DEPARTMENT OF PIPER RUDNICK LLP  
ONE LIBERTY PLACE, SUITE 4900  
1650 MARKET ST  
PHILADELPHIA, PA 19103

EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/898,292	<b>Applicant(s)</b> AMOUYAL, MICHELE	
	<b>Examiner</b> Heather G. Calamita, Ph.D.	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-14, 16-23 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14, 16-23 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The response to the official action dated February 13, 2004 has been received and entered in full.

Claims 11-14, 16-23 and 27 are under examination. Claims 1-10, 15 and 24-26 have been canceled.

After an updated search new prior art relevant to the pending claims was found.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 recites the limitation "concentration (C)" in line 2. There is insufficient antecedent basis for this limitation in the claim. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-14, 16-18, 22, 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodgson et al. (USPN 6,410,220 B1 06/25/2002).

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Hodgson et al. teach a method for preparing circularized recombinant nucleic acids from a vector and an insert by ligating a DNA insert and a DNA vector in the presence of a DNA compaction agent selected from the group consisting of histone proteins, histone protein derivatives, viral envelope proteins, bacterial chromoid proteins, non-histone chromosomal proteins, HMGs derivatives of said proteins, and mixtures of said proteins and protein derivatives and selecting said circularized recombinant nucleic acid (see whole document, especially col. 23 lines 17-27). With regard to claims 12 and 27, they teach the circularized recombinant nucleic acid as greater than 5 and 10 kb (see col. 23 lines 22-24). With regard to claim 13, they teach the selection steps of transferring the circularized recombinant nucleic acid into a cellular medium, cloning nucleic acid, and testing for the presence of the insert in the circularized recombinant nucleic acid (see col. 23 lines 22-27). With regard to claim 14, they teach the DNA compaction agent is selected from the group consisting of a protein, a mixture of proteins and protein derivatives exhibiting the properties of the DNA compaction agent (see col. 23 lines 49-51). With regard to claims 16, 17, 18, they teach adding a ligase to a ligation medium containing the DNA in solution in ligation buffer or adding the compaction agent to the ligation medium prior to the addition of ligase or adding the ligase and the compaction agent simultaneously (see col. 23 line 52). With regard to claim 22, they teach the ligation medium comprising a stabilizing agent that prevents denaturation, aggregation, and absorption of the DNA compaction agent (see col. 23 line 52). With regard to claim 23, they teach histone proteins (see col. 23 line 51).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodgson et al. (USPN 6,410,220 B1 06/25/2002) in view of Nagaki et al. (BBRC 246:137-141, 1998).

The teachings of Hodgson et al. are described previously.

Hodgson et al. do not teach a specific amount of HMG to use in the ligation reaction.

Nagaki et al. do teach using a range of 0.5 µg to 2.0 µg of HMG in the ligation reaction (see whole document, especially Fig. 2, page 139).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Nagaki's method of using a range of HMG concentrations with Hodgson's method of ligating insert and vector DNA in order to determine the amount of protein needed for the reaction. Nagaki et al. state that HMG1 and HMG2 stimulate cohesive-end and blunt-end ligations with DNA ligase (see col. 2 2<sup>nd</sup> paragraph pp 137-138). It would have been prima facie obvious to apply Nagaki's range of HMG concentrations with Hodgson's method for ligating insert and vector DNA to achieve the expected advantage of achieving optimal ligation activity with a given amount of DNA and HMG.

### ***Conclusion***


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Mondays thru Thursdays 7:00 A.M. - 5:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
3/7/04